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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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08/945,144 01/20/98 LEBRUN

M RP/PCT

EXAMINER

HM12/0614

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WILMINGTON DE 19899-2207

KEUSE, D

ART UNIT

PAPER NUMBER

1638

DATE MAILED:

06/14/01

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

08/945,144

Applicant(s)

LEBRUN ET AL.

Examiner

David H Kruse

Art Unit

1638

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 14 May 2001.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 36-41 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 36-41 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: _____

DETAILED ACTION

1. Cancellation of claims 30-35 and the addition of claims 36-41 in Paper No. 20 filed 14 May 2001 is acknowledged. Claims 36-41 are pending.

Response to Arguments

Double Patenting

2. The Obviousness-Type Double Patenting rejection of Claims 30-35 is now moot. In addition, Applicant's arguments are deemed persuasive in view of the claimed subject matter in copending Application 08/945,821. At this time, copending Application 08/945,821 stands abandoned.

Response to Amendments

Sequence Rules

3. The Specification now appears to comply with the Sequence Rules in view of the Amendment filed 14 May 2001.

Specification

4. The abstract of the disclosure is objected to because it is not descriptive within the breadth of the claims. Correction is required. See MPEP § 608.01(b).

Claim Objections

5. Claim 41 is objected to because of the following informalities: At line 2, the phrase "a plant" should read -- the plant -- in reference to the transgenic plant of Claim 39. Appropriate correction is required.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. § 112:

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The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 36-41 are rejected under 35 U.S.C. § 112, first paragraph, because the specification, while being enabling for a maize DNA sequence encoding a modified 5-enolpyruvylshikimate-3-phosphate synthase, vectors, bacteria, transgenic plants and plant cells comprising said DNA sequence, and a method of protecting plants comprising said transgenic plants, does not reasonably provide enablement for all DNA sequences encoding a modified 5-enolpyruvylshikimate-3-phosphate synthase, vectors, bacteria, transgenic plants and plant cells comprising said DNA sequence. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Applicant claims an isolated or modified DNA encoding a mutant 5-enolpyruvylshikimate-3-phosphate synthase, vectors and transformed cells and plants comprising said DNA and a method of protecting plants comprising said DNA.

Applicant describes a modified maize DNA sequence encoding a mutated 5-enolpyruvylshikimate-3-phosphate synthase.

Applicant does not describe other modified DNA sequences encoding a mutant 5-enolpyruvylshikimate-3-phosphate synthase.

Hence, it is unclear from the instant specification that Applicant was in possession of the invention as broadly claimed.

See *University of California V. Eli Lilly and Co.*, 43 USPQ2d 1398 (Fed. Cir. 1997), which teaches that the disclosure of a process for obtaining cDNA from a particular organism and the description of the encoded protein fail to provide an adequate written description of the actual cDNA from that organism which would encode the protein from that organism, despite the disclosure of a cDNA encoding that protein from another organism.

7. Claims 36-41 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicant claims an isolated or modified DNA encoding a mutant 5-enolpyruvylshikimate-3-phosphate synthase, vectors and transformed cells and plants comprising said DNA and a method of protecting plants comprising said DNA.

Applicant teaches a modified maize DNA sequence encoding a mutated 5-enolpyruvylshikimate-3-phosphate synthase and transformed bacterial and plant cells comprising said modified DNA.

Applicant does not teach other modified DNA sequences encoding a mutant 5-enolpyruvylshikimate-3-phosphate synthase or transformed host cells other than bacterial and plant cells.

In re Wands, 858F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988) lists eight considerations for determining whether or not undue experimentation would be necessary to practice an invention. These factors are: the quantity of experimentation

necessary, the amount of direction or guidance presented, the presence or absence of working examples of the invention, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art, and the breadth of the claims.

Applicant has only provided guidance for isolation and modification of a maize EPSPS encoding gene. In addition, Applicant has only taught transformation of bacterial and plant cells comprising a modified maize EPSPS encoding gene. The state of the art for modification of enzyme in order to produce herbicide resistance at the time of Applicant's invention required extensive guidance for one of ordinary skill in the art to practice the invention within the broad scope of the claims. Hence, it would have required undue trial and error experimentation for one of ordinary skill in the art at the time of Applicant's invention to isolate all DNA sequences encoding a 5-enol pyruvylshikimate-3-phosphate synthase, modify said DNA sequences while preserving enzyme activity, screen through the myriad of modified DNA sequences to identify those that are tolerant to glyphosate, transform plants or other cells with the identified DNA sequences and determine which modified DNA sequences that would protect said transformed plants from herbicide damage.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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9. Claims 36-41 are rejected under 35 U.S.C. § 102(b) as being anticipated by Shah *et al* (US Patent 5,188,642).

Shah discloses an isolated and modified DNA encoding a mutated *Arabidopsis* 5-enolpyruylshikimate-3-phosphate synthase gene, a vector comprising said DNA and a transgenic plant cell comprising said DNA (Example 21, columns 34 and 35). In addition, Shah discloses a method of protecting plants from herbicidal damage (Claim 1, column 37) and a transgenic maize plant comprising said DNA (column 3, line 53). Hence, all of the claim limitations were previously disclosed by Shah.

Conclusion

10. No Claims are allowed.
11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR § 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR § 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David H. Kruse, Ph.D. whose telephone number is (703) 306-4539. The examiner can normally be reached on Monday to Friday from 8:00 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Paula Hutzell can be reached at (703) 308-4310. The fax telephone number for this Group is (703) 308-4242 or (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the William Phillips whose telephone number is (703) 305-3419.

David H. Kruse, Ph.D.
7 June 2001



AMY J. NELSON, PH.D.
PRIMARY EXAMINER